



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/963,288	11/03/1997	GUNNAR NORSTEDT	10806-48	9881

7590 09/10/2003

HOLLY D KOZLOWSKI  
DINSMORE AND SHOHL  
1900 CHEMED CENTER  
255 EAST FIFTH STREET  
CINCINNATI, OH 45202

[REDACTED] EXAMINER

FALK, ANNE MARIE

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1632

H2

DATE MAILED: 09/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	08/963,288	NORSTEDT ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Anne-Marie Falk, Ph.D.	1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 05 May 2003.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1,2,8-11,16,17,19-21,34-36,39-42,44-48,50,52 and 55-69 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 1,2,8-11,16,17,19-21,34-36,39-42,44-48,50,52,55,60 and 65 is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                              | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____                                    |

Art Unit: 1632

## DETAILED ACTION

The amendment filed May 5, 2003 (Paper No. 41) has been entered. Claims 5, 7, 15, 23-32, 49, and 53 have been cancelled. Claims 55-69 have been newly added.

Accordingly, Claims 1, 2, 8-11, 16, 17, 19-21, 34-36, 39-42, 44-48, 50, 52, and 55-69 are pending in the instant application.

The numbering of claims is not accordance with 37 CFR 1.126, which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not). Claim 54 was added by the amendment submitted August 31, 2000. Misnumbered claims 54-68 have been renumbered as claims 55-69, respectively. However, Applicant is responsible for making any necessary amendments to correct the claim dependencies.

The following rejections are reiterated or newly applied and constitute the complete set of rejections being applied to the instant application. Rejections and objections not reiterated from the previous office action are hereby withdrawn.

### *Specification*

The amendment filed 10/28/02 stands objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the amendment at pages 2 to 3 changing 50 bp to 52 bp.

Applicant is required to cancel the new matter in the reply to this Office Action.

Art Unit: 1632

No evidence is offered in support of the amendments to Examples 1, 2, and 3. While it is evident that the sequence set forth on page 2, paragraph 3, designated SEQ ID NO: 1, is 52 bp, not 50 bp, it is not evident that the element used in the experiments was the full 52 bp sequence. The specification as-filed consistently reports that a 50 bp element was used in the experiments presented in Examples 1-3. No evidence has been provided to support the amendment to the specification.

At page 7 of the response of October 28, 2002, Applicants point to the specification at page 2, paragraph 3 which discloses a sequence 52 bp in length, but refers to it as “the 50 bp SPI-GHRE.” However, it is unclear where the error occurred, whether it was with disclosing SEQ ID NO: 1 as a 52 bp element when it should have been a 50 bp element or the other way around as Applicants seem to be arguing in their response. The specification clearly states in Example 2 that “a 50 bp growth hormone responsive element” (emphasis added) was used in preparing the expression plasmid and that the SPI-GHRE element is 50 bp in length. See specification at page 3, line 31 where it refers to the “50 bp element named SPI-GHRE” (emphasis added). Attorney argument cannot substitute for evidence. No evidence has been submitted to attest to the use of a 52 bp element rather than a 50 bp element in the working examples. Applicants are invited to submit a declaration to support the proposed amendment to the specification. However, as noted above, Applicant is required to cancel the new matter in reply to this Office Action. Any evidence submitted will be evaluated in view of the proposed amendment.

At pages 12-13 of the current response, Applicants argue that one of ordinary skill in the art would readily recognize that the 50 bp SPI-GHRE element referred to in the specification was actually 52 bp. On the contrary, due to the inconsistencies of the specification, one of skill in the art would not know if the experiments described were performed with a 52 bp element or a 50 bp element. Attorney argument cannot substitute for evidence.

Art Unit: 1632

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 56-59, 61-64, and 66-69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 56-59 are indefinite because they depend from Claim 54 which has been cancelled.

Claims 61-64 are indefinite because they depend from Claim 59 which depends from Claim 54 which has been cancelled.

Claims 66-69 are indefinite because they depend from Claim 64 which depends from Claim 59 which depends from Claim 54 which has been cancelled.

### *Conclusion*

Claims 1, 2, 8-11, 16, 17, 19-21, 34-36, 39-42, 44-48, 50, 52, 55, 60, and 65 are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 1632

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (703) 306-9155. The examiner can normally be reached Monday through Thursday and alternate Fridays from 10:00 AM to 7:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, William Phillips, whose telephone number is (703) 305-3482.

Anne-Marie Falk, Ph.D.

*Anne-Marie Falk*  
ANNE-MARIE FALK, PH.D  
PRIMARY EXAMINER